

“(ii) there is a submitted application that could be approved under the criteria of section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j));

“(iii) there is no patent protection or market exclusivity protection under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.); or

“(iv) there is a referral for inclusion on the list under section 505A(d)(4)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a(d)(4)(C)); and

“(B) in the case of a drug referred to in clause (i), (ii), or (iii) of subparagraph (A), additional studies are needed to assess the safety and effectiveness of the use of the drug in the pediatric population.

“(2) CONSIDERATION OF AVAILABLE INFORMATION.—In developing and prioritizing the list under paragraph (1), the Secretary shall consider, for each drug on the list—

“(A) the availability of information concerning the safe and effective use of the drug in the pediatric population;

“(B) whether additional information is needed;

“(C) whether new pediatric studies concerning the drug may produce health benefits in the pediatric population; and

“(D) whether reformulation of the drug is necessary;

“(b) CONTRACTS FOR PEDIATRIC STUDIES.—The Secretary shall award contracts to entities that have the expertise to conduct pediatric clinical trials (including qualified universities, hospitals, laboratories, contract research organizations, federally funded programs such as pediatric pharmacology research units, other public or private institutions, or individuals) to enable the entities to conduct pediatric studies concerning one or more drugs identified in the list described in subsection (a).

“(c) PROCESS FOR CONTRACTS AND LABELING CHANGES.—

“(1) WRITTEN REQUEST TO HOLDERS OF APPROVED APPLICATIONS FOR DRUGS LACKING EXCLUSIVITY.—The Commissioner of Food and Drugs, in consultation with the Director of the National Institutes of Health, may issue a written request (which shall include a timeframe for negotiations for an agreement) for pediatric studies concerning a drug identified in the list described in subsection (a)(1)(A) (except clause (iv)) to all holders of an approved application for the drug under section 505 of the Federal Food, Drug, and Cosmetic Act. Such a request shall be made in accordance with section 505A of the Federal Food, Drug, and Cosmetic Act.

“(2) REQUESTS FOR CONTRACT PROPOSALS.—If the Commissioner of Food and Drugs does not receive a response to a written request issued under paragraph (1) within 30 days of the date on which a request was issued, or if a referral described in subsection (a)(1)(A)(iv) is made, the Secretary, acting through the Director of the National Institutes of Health and in consultation with the Commissioner of Food and Drugs, shall publish a request for contract proposals to conduct the pediatric studies described in the written request.

“(3) DISQUALIFICATION.—A holder that receives a first right of refusal shall not be entitled to respond to a request for contract proposals under paragraph (2).

“(4) GUIDANCE.—Not later than 270 days after the date of enactment of this section, the Commissioner of Food and Drugs shall promulgate guidance to establish the process for the submission of responses to written requests under paragraph (1).

“(5) CONTRACTS.—A contract under this section may be awarded only if a proposal for the contract is submitted to the Secretary in such form and manner, and containing such agreements, assurances, and information as

the Secretary determines to be necessary to carry out this section.

“(6) REPORTING OF STUDIES.—

“(A) IN GENERAL.—On completion of a pediatric study in accordance with a contract awarded under this section, a report concerning the study shall be submitted to the Director of the National Institutes of Health and the Commissioner of Food and Drugs. The report shall include all data generated in connection with the study.

“(B) AVAILABILITY OF REPORTS.—Each report submitted under subparagraph (A) shall be considered to be in the public domain (subject to section 505A(d)(4)(D)) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a(d)(4)(D)) and shall be assigned a docket number by the Commissioner of Food and Drugs. An interested person may submit written comments concerning such pediatric studies to the Commissioner of Food and Drugs, and the written comments shall become part of the docket file with respect to each of the drugs.

“(C) ACTION BY COMMISSIONER.—The Commissioner of Food and Drugs shall take appropriate action in response to the reports submitted under subparagraph (A) in accordance with paragraph (7).

“(7) REQUESTS FOR LABELING CHANGE.—During the 180-day period after the date on which a report is submitted under paragraph (6)(A), the Commissioner of Food and Drugs shall—

“(A) review the report and such other data as are available concerning the safe and effective use in the pediatric population of the drug studied;

“(B) negotiate with the holders of approved applications for the drug studied for any labeling changes that the Commissioner of Food and Drugs determines to be appropriate and requests the holders to make; and

“(C)(i) place in the public docket file a copy of the report and of any requested labeling changes; and

“(ii) publish in the Federal Register a summary of the report and a copy of any requested labeling changes.

“(8) DISPUTE RESOLUTION.—

“(A) REFERRAL TO PEDIATRIC ADVISORY COMMITTEE.—If, not later than the end of the 180-day period specified in paragraph (7), the holder of an approved application for the drug involved does not agree to any labeling change requested by the Commissioner of Food and Drugs under that paragraph, the Commissioner of Food and Drugs may refer the request to the Pediatric Advisory Committee.

“(B) ACTION BY THE PEDIATRIC ADVISORY COMMITTEE.—Not later than 90 days after receiving a referral under subparagraph (A), the Pediatric Advisory Committee shall—

“(i) review the available information on the safe and effective use of the drug in the pediatric population, including study reports submitted under this section; and

“(ii) make a recommendation to the Commissioner of Food and Drugs as to appropriate labeling changes, if any.

“(9) FDA DETERMINATION.—Not later than 30 days after receiving a recommendation from the Pediatric Advisory Committee under paragraph (8)(B)(ii) with respect to a drug, the Commissioner of Food and Drugs shall consider the recommendation and, if appropriate, make a request to the holders of approved applications for the drug to make any labeling change that the Commissioner of Food and Drugs determines to be appropriate.

“(10) FAILURE TO AGREE.—If a holder of an approved application for a drug, within 30 days after receiving a request to make a labeling change under paragraph (9), does not agree to make a requested labeling change, the Commissioner may deem the drug to be

misbranded under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).

“(11) NO EFFECT ON AUTHORITY.—Nothing in this subsection limits the authority of the United States to bring an enforcement action under section 502 when a drug lacks appropriate pediatric labeling.

“(12) RECOMMENDATION FOR FORMULATION CHANGES.—If a pediatric study completed under public contract indicates that a formulation change is necessary and the Secretary agrees, the Secretary shall send a nonbinding letter of recommendation regarding that change to each holder of an approved application.

“(d) AUTHORIZATION OF APPROPRIATIONS.—

“(1) IN GENERAL.—There are authorized to be appropriated to carry out this section—

“(A) \$200,000,000 for fiscal year 2002; and

“(B) such sums as are necessary for each of the 5 succeeding fiscal years.

“(2) AVAILABILITY.—Any amount appropriated under paragraph (1) shall remain available to carry out this section until expended.”.

SEC. 4. WRITTEN REQUEST TO HOLDERS OF APPROVED APPLICATIONS FOR DRUGS THAT HAVE MARKET EXCLUSIVITY.

Section 505A(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a(d)) is amended by adding at the end the following:

“(4) WRITTEN REQUEST TO HOLDERS OF APPROVED APPLICATIONS FOR DRUGS THAT HAVE MARKET EXCLUSIVITY.—

“(A) REQUEST AND RESPONSE.—If the Secretary makes a written request for pediatric studies (including neonates, as appropriate) under subsection (c) to the holder of an application approved under section 505(b)(1), the holder, not later than 180 days after receiving the written request, shall respond to the Secretary as to the intention of the holder to act on the request by—

“(i) indicating when the pediatric studies will be initiated, if the holder agrees to the request; or

“(ii) indicating that the holder does not agree to the request.

“(B) NO AGREEMENT TO REQUEST.—

“(i) REFERRAL.—If the holder does not agree to a written request within the time period specified in subparagraph (A), and if the Secretary determines that there is a continuing need for information relating to the use of the drug in the pediatric population (including neonates, as appropriate), the Secretary shall refer the drug to the Foundation for the National Institutes of Health established under section 499 of the Public Health Service Act (42 U.S.C. 290b) (referred to in this paragraph as the ‘Foundation’) for the conduct of the pediatric studies described in the written request.

“(ii) PUBLIC NOTICE.—The Secretary shall give public notice of the name of the drug, the name of the manufacturer, and the indications to be studied made in a referral under clause (i).

“(C) LACK OF FUNDS.—On referral of a drug under subparagraph (B)(i), the Foundation shall issue a proposal to award a grant to conduct the requested studies unless the Foundation certifies to the Secretary, within a timeframe that the Secretary determines is appropriate through guidance, that the Foundation does not have funds available to conduct the requested studies. If the Foundation so certifies, the Secretary shall refer the drug for inclusion on the list established under section 409I of the Public Health Service Act for the conduct of the studies.

“(D) EFFECT OF SUBSECTION.—Nothing in this subsection (including with respect to referrals from the Secretary to the Foundation) alters or amends section 301(j) of this Act or section 552 of title 5 or section 1905 of title 18, United States Code.